

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/594,119	SHINYA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	GALINA YAKOVLEVA	1641

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 07/21/2011.
2. ☒ The allowed claim(s) is/are 28,33,36-39,41 and 42.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\* c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. <input type="checkbox"/> Notice of References Cited (PTO-892)	5. <input type="checkbox"/> Notice of Informal Patent Application
2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)	6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>20110728</u> .
3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____	7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment
4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance
	9. <input type="checkbox"/> Other _____.
/SHAFIQU L HAQ/ Primary Examiner, Art Unit 1641	

### **DETAILED ACTION**

Responsive to communication entered 07/21/2011.

#### ***Status of Claims***

Claims 28, 33, 36-39, 41 and 42 are pending. Claims 28, 33, 36-39, 41 and 42 are allowed.

#### ***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Thomas W. Cole on 07/27/2011.

The application has been amended as follows:

1. At page 9, paragraph [0023], after "Asp-Tyr-Lys-Asp-Asp-Asp-Asp-Lys" insert --(SEQ ID No. 1)--.
2. At page 20, paragraph [0067], after "Asp-Tyr-Lys-Asp-Asp-Asp-Asp-Lys" insert --(SEQ ID No. 1)--.
3. At page 24, paragraph [0084], after "Asp-Tyr-Lys-Asp-Asp-Asp-Asp-Lys" insert --(SEQ ID No. 1)--.
4. In Claim 28, line 7, before "binding" insert --covalently--.
5. In Claim 39, line 4, after "formula" delete -- , --.
6. In Claim 39, line 6, after "formula" delete -- , --.

Art Unit: 1641

7. In Claim 42, line 2, after "Asp-Tyr-Lys-Asp-Asp-Asp-Asp-Lys" delete -- . --.
8. In Claim 42, line 5, after "(SEQ ID No. 1)" insert -- . --.

***Withdrawn Objections/Rejections***

- I. The objection to Claim 42 is withdrawn in view of Applicant's amendment of the claim.
- II. The rejection of Claims 32, 33 and 39 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's cancellation of Claim 32 and amendment of Claims 33 and 39.
- III. The rejection of Claims 32, 33 and 39 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's cancellation of Claim 32 and amendment of Claims 33 and 39.

***Examiner's Statement of Reasons for Allowance of Claims 28, 33, 36-39, 41 and 42***

Claims 28, 33, 36-39, 41 and 42 are allowed because the prior art does not teach or fairly suggest a method for capturing a biological substance comprising at least the following: (A) guiding a sample solution containing a complex of the biological substance and a chimeric substance to a region of a solid surface, the chimeric substance comprising a probe substance, except a peptide or protein, capable of interacting with the biological substance, an epitope tag peptide recognized by an antibody, which antibody is immobilized to a solid surface, and an organic compound having a chemical structure capable of covalently binding to both the probe substance and the epitope tag peptide; (B) enabling the interaction of said antibody immobilized to

Art Unit: 1641

the solid surface with the epitope tag peptide in the chimeric substance included in the complex.

The chimeric substance of the instant invention functions as a reversibly detachable bridge between a biological substance to be captured and an antibody immobilized on the solid surface. The reversibly detachable bridge makes it possible to dissociate, dilute and recover the biological substance.

The avidin-biotin binding system is well-known in the art. See, for example, U.S. Patent App. Pub. No. 2006/0234229 to Van Beuningen *et al.* (of record).

The fused protein-epitope tag peptide technology, also well-known in the art, is based on construction of a fusion protein with an epitope tag peptide, such as a FLAG affinity tag. See, for example, Einhauer, A.; Jungbauer, A.; "The FLAG peptide, a versatile fusion tag for the purification of recombinant proteins", Journal of Biochemical and Biophysical Methods, 2001, vol. 49, pp.455-465 (IDS entered 06/12/2009). A small FLAG sequence is cloned into the protein under study. The sequence binds to immobilized antibody directed against the FLAG sequence. After some washing steps, elution is effected with a peptide that competes for binding site on an anti-FLAG antibody.

### ***Conclusion***

Claims 28, 33, 36-39, 41 and 42 are allowed.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

Art Unit: 1641

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GALINA YAKOVLEVA whose telephone number is (571)270-3282. The examiner can normally be reached on Monday-Friday 8:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. Y./

Examiner, Art Unit 1641

/SHAFIQUL HAQ/

Primary Examiner, Art Unit 1641